UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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FERRING B.V., FERRING INTERNATIONAL CENTER S.A., AND FERRING PHARMACEUTICALS INC.,

Plaintiffs,

-against-

ALLERGAN, INC., ALLERGAN USA, INC., ALLERGAN SALES, LLC, SERENITY PHARMACEUTICALS CORPORATION, SERENITY PHARMACEUTICALS, LLC, REPRISE BIOPHARMACEUTICS, LLC, SEYMOUR H. FEIN, AND RONALD V. NARDI,

Defendants.

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12 Civ. 2650

SEALED OPINON

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Plaintiffs Ferring B.V., Ferring Int'l Center S.A., and Ferring Pharmaceuticals (collectively, "Ferring" or "Plaintiffs") have moved for summary judgment dismissing the counterclaims of Allergan Inc., Allergan USA, Inc., Allergan Sales, LLC (collectively "Allergan" or "Defendants") to correct the inventorship of Patent Nos. 7,560,429 and 7,947,654 (collectively, the "Patents"). For the reasons set forth below, the motion is granted in part and denied in part.

I. Prior Proceedings

Familiarity with the prior proceedings and facts as alleged in the initial complaint filed by Ferring on April 5, 2012 is assumed and were set forth in the March 18, 2013 order (the "March 18 Order") granting Defendants' motion to dismiss. See generally Ferring B.V. v. Allergan, Inc., 932 F. Supp. 2d 493 (S.D.N.Y. 2013) reconsideration denied, No. 12 CIV. 2650 (RWS), 2013 WL 4082930 (S.D.N.Y. Aug. 7, 2013). Thereafter, on April 16, 2013, Ferring moved for reconsideration, or in the alternative, leave to file an amended complaint. The motion was denied on August 7, 2013, with leave granted to permit Ferring to move for leave to amend in compliance with the March 18

Order. Ferring B.V. v. Allergan, Inc., No. 12 CIV. 2650 (RWS), 2013 WL 4082930 (S.D.N.Y. Aug. 7, 2013). On August 22, 2013, Ferring moved to amend the complaint. The motion was denied in its entirety on March 13, 2014. Ferring B.V. v. Allergan, Inc., 4 F. Supp. 3d 612 (S.D.N.Y. 2014).

Given the extensive factual background detailed in this Court's other decisions, the following facts provide only a summary retelling of undisputed events for purposes of approaching the instant motion.[1]

Desmopressin is a synthetic analogue to vasopressin, a human hormone antidiuretic that regulates hydration and water reabsorption by the kidneys. In 1987, Ferring introduced oral tablets containing desmopressin for treatment of certain urinary disorders. In some patients, desmopressin had the undesirable side effect of hyponatremia, low sodium ion concentration in the

[1] The facts that follow are drawn from filings in this case and are not in material dispute except as noted. Denials in the 56.1 statements that the evidence cited in support of a particular statement does not support that statement, in instances where the evidence uncontrovertibly does support that statement, are treated as admissions. Denials without support or explanation are treated as admissions. The inclusion of facts or statements in this Opinion that were challenged on evidentiary grounds by the parties reflect a ruling that the evidentiary challenge is overruled.

blood. Ferring continued research on forms of desmopressin throughout the 1990s. By June 1999, Ferring had expressed an intent to pursue a feasibility study for a quick-dissolving sublingual, or orodispersible,[2] form of desmopressin. By January 2001, Ferring had summarized its feasibility study. After months of testing, by May 2001 Ferring had confirmed the feasibility of an orodispersible formulation of desmopressin using a fish gelatin matrix, and by August Ferring signed a development contract to manufacture the form. Dr. Fein did not participate in any of this development work for an orodispersible formulation of desmopressin.

Dr. Fein first became involved with development of desmopressin at Ferring in August 2001.[3] Thereafter, Ferring scientists designed a clinical study to investigate the

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[2] Orodispersible formulations are "solid unit dosage forms, which disintegrate in the mouth within a minute in the presence of saliva due to super disintegrants in the formulation." Paramita Dey & Sabyasachi Maiti, Orodispersible tablets: A new trend in drug delivery, J. Nat. Sci. Biol. Med., July-Dec. 2010, at 2-5. Sublingual tablets are therefore a subgenre of orodispersible tablets, but not all orodispersible medications are necessarily sublingual.

[3] Ferring contends Dr. Fein did not participate before August 2001. Allergan disputes this statement in their 56.1 Response, as evidenced by Fein's deposition reference to "the summer of 2001." Defs.' Response to 56.1 Statement at 6, ¶ 29 ("Allergan 56.1"). However, Allergan admits elsewhere that "Dr. Fein became involved in Ferring's desmopressin research in August 2001." Defs.' Opp. at 1.

bioavailability of Ferring's orodispersible desmopressin dose form, designated CS004. The parties dispute whether Dr. Fein was active in designing that study. CS004 tested the formulation work Ferring had done between 2000 and 2001, and ultimately demonstrated that the orodispersible dose form demonstrated improved bioavailability of desmopressin.

On May 7, 2002, Ferring filed Great Britain Patent Application No. GB0210397.6. Decl. of John W. Cox in Supp. of Ferring's Mot. for Summary Judgment ("Cox Decl."), Ex. 31 ("GB Application."). The GB Application disclosed a "pharmaceutical dosage form of desmopressin adapted for sublingual absorption." It named no individual inventors. A series of patent filings by Ferring and Fein ensued.[4]

On September 20, 2002, Ferring filed PCT application IB02/04036, claiming the same subject matter as the Great Britain 0210397.6 application and listed Dr. Fein among the inventors. On May 7, 2003, Ferring filed a modified PCT

[4] Only the filings relevant to the patents at issue in this motion, '429 and '654, will be discussed. For a full recitation of all the patent filings relevant to Ferring and Fein's claims to formulations of desmopressin, see Ferring B.V. v. Allergan, Inc., No. 12 CIV. 2650, 2015 WL 5671799, at *2-7 (S.D.N.Y. Sept. 22, 2015).

application IB03/02368, which did not name Fein. PCT/IB03/02368 matured into U.S. patent application 10/513,437, with a filing date of May 7, 2003. On June 18, 2009, Ferring filed U.S. patent application 12/487,116 as a continuation of application 10/513,437. On July 14, 2009 Ferring's U.S. patent application 10/513,437 issued as U.S. Patent No. 7,560,429. Cox Decl. Ex. 13 (the "'429 Patent").

On June 18, 2009, Ferring filed U.S. patent application 12/487,116 as a continuation of its previously filed U.S. patent application 10/513,437. In a Preliminary Amendment dated November 6, 2009, Ferring amended U.S. Patent Application No. 12/487,116 to add claims directed to "[a]n orodispersible pharmaceutical dosage form of desmopressin acetate which disintegrates in the mouth within 10 seconds." Ferring added a dependent claim that additionally limited this "orodispersible pharmaceutical dosage form of desmopressin acetate which disintegrates in the mouth within 10 seconds" to one "which is adapted for sublingual administration." Ferring did not add back Dr. Fein as an inventor when it reinserted a claim to U.S. patent application 12/487,116 for desmopressin adapted for sublingual administration. On May 24, 2011, Ferring's U.S.

patent application 12/487,116 issued as U.S. Patent No. 7,947,654. Cox Decl., Ex. 14 ("the '654 patent").

Allergan, the assignee of Dr. Fein's interest in the '429 and '654 patents, in its First Amended Answer to Plaintiffs' First Amended Complaint filed April 3, 2014 (the "FAA"), counterclaimed pursuant to 35 U.S.C. § 256 to correct the inventorship of the '429 and '654 patents to substitute Dr. Fein as the sole inventor, or in the alternative, to add Dr. Fein as a joint inventor. Ferring filed a motion for summary judgment to dismiss all of these counterclaims on September 10, 2015. Oral argument was held and the motion deemed fully submitted on December 12, 2015.

II. Applicable Standard

Summary judgment is appropriate only where "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). A dispute is "genuine" if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The relevant inquiry on application for summary judgment is "whether

the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." Id. at 251-52. A court is not charged with weighing the evidence and determining its truth, but with determining whether there is a genuine issue for trial. Westinghouse Elec. Corp. v. N.Y. City Transit Auth., 735 F. Supp. 1205, 1212 (S.D.N.Y. 1990) (quoting Anderson, 477 U.S. at 249). "[T]he mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." Anderson, 477 U.S. at 247-48 (emphasis in original).

"[T]he substantive law will identify which facts are material." Id. at 248. In this case, there must be a genuine dispute of material fact as to whether Fein invented or contributed to the inventions in the Patents. "The general rule is that a party alleging misjoinder or non-joinder of inventors must meet the heavy burden of proving its case by clear and convincing evidence, and must provide evidence to corroborate the alleged joint inventor's conception." Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1358 (Fed. Cir. 2004) (citing Hess v. Advanced Cardiovascular Sys., Inc., 106 F.3d 976, 980

(Fed.Cir.1997) (citing Garrett Corp. v. United States, 190 Ct.Cl. 858, 422 F.2d 874, 880 (1970)); Ethicon, Inc. v. United States Surgical Corp., 135 F.3d 1456, 1461 (Fed.Cir.1998) (internal citations omitted)). "The inventors as named in an issued patent are assumed to be correct." Hess, 106 F.3d at 980 (citation omitted); see also Eli Lilly & Co., 376 F.3d at 1358. The standard to correct inventorship is set deliberately high. As the Federal Circuit has explained: "there is [a]. . . strong temptation for persons who consulted with the inventor and provided him with materials and advice, to reconstruct, so as to further their own position, the extent of their contribution to the conception of the invention. In these circumstances, it would be inappropriate to permit a lower standard than clear and convincing evidence." Hess, 106 F.3d at 980.

III. Summary Judgment in Favor of Ferring is Granted for the Counterclaims to Add Dr. Fein as a Sole Inventor

a. The '429 Patent

The '429 Patent recites 19 claims, the first six of which are as follows:[5]

[5] It is common for the terms "dose" and "dosage" to be used

1. An orodispersible solid pharmaceutical dosage form of desmopressin acetate, wherein said dosage form (A) disintegrates in the mouth within 10 seconds and (B) comprises an amount of desmopressin, measured as the free base, selected from the group consisting of 25µg, 50µg, and 75 µg.
2. A dosage form as claimed in claim 1, wherein the dosage form comprises desmopressin acetate and an open matrix network carrying the desmopressin acetate, wherein the open matrix network is comprised of a water-soluble or water-dispersible carrier material that is inert towards desmopressin acetate.
3. A dosage form as claimed in claim 2, wherein the open matrix network comprises gelatin.
4. A dosage form as claimed in claim 3, wherein the gelatin is fish gelatin.
5. A dosage form as claimed in claim 4, wherein the fish gelatin is non-gelling.
6. A process for preparing an orodispersible solid pharmaceutical dosage form of desmopressin acetate which disintegrates in the mouth within 10 seconds and which comprises an amount of desmopressin, measured as the free base, selected from the group consisting of 25µg, 50µg, and 75 µg, said process comprising subliming solvent from a composition comprising desmopressin acetate and a solution of carrier material in the solvent, wherein the composition is in the solid state in a mold.

Id. at 17:49-18:9. The claims go on to address subliming by freeze drying, solvent and pH range, packaging, and treatment purposes.

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interchangeably, though the terms are not synonyms. To be precise, a "dose" indicates quantity, as in a 325 milligram dose of aspirin. "Dosage" indicates a rate of application of a dose, as in one tablet of 325 milligrams of aspirin per day for a week. Though some material quoted herein appears to muddle the distinction, the Court uses "dose," not "dosage," to refer to a numerically defined (or numerically relative) quantity of desmopressin.

Allergan has pled solely that "each claim of the '429 Patent recites Dr. Fein's invention of low doses of desmopressin." FAA ¶ 54, 56. Allergan has not pled Fein invented any other concepts, specifications, or formulations in the '429 patent. In fact, Allergan explicitly admits that Fein did not contribute certain aspects of the '429 Patent claims. See e.g. Defs.' Allergan 56.1 at ¶27 (regarding recommendations related to the formulation of orodispersible desmopressin), ¶ 60 (regarding the 25, 50, and 75 microgram doses).

Even accepting as true that the general concept of low-dose administration of desmopressin, standing alone and without specific doses, is an "invention" patented in the '429 Patent and that Fein invented it, a comparison of the '429 Patent Claims and Allergan's allegations demonstrates easily that, unless no other element of the patent was novel, Fein cannot be the sole inventor named for the patent which contains a great deal more than a general contribution of "low dose." Yet, no argument set forth in Allergan's opposition papers bridges the gap between the Fein's claimed invention and the totality of the '429 Patent.

Allergan argues that sublingual administration and low dose were the only novel and significant aspects of the claimed inventions in both patents.[6] The '429 Patent specifies numerical low doses of desmopressin of 25, 50, and 75 micrograms, not a broad concept of a "low dose." See '429 Patent 17:49-18:63. Allergan does not dispute the following testimony of Dr. Fein:

> Q: Did you ever recommend to anyone at Ferring that they use doses of 25, 50, and 75 micrograms of the melt formulation?
> A: I don't recall recommending to Ferring the use of those specific doses.

Allergan's 56.1 ¶ 60. Allergan conceded at oral argument Fein did not pick the doses, in fact no one did.[7] Allergan's argument is therefore premised on the notion that the doses in the patent "are exemplary of the low dose Fein invented."[8]

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[6] Allergan argues nominally in its First Amended Answer that "Dr. Fein alone invented the use of low doses of desmopressin and the sublingual administration of desmopressin claimed in the '429 Patent." FAA ¶ 70. In its 56.1, Allergan admits "None of the '429 Patent claims recite 'sublingual administration.'" Allergan 56.1 at 7, ¶ 38. Allergan's claim with respect to the '429 Patent is therefore limited to Fein's alleged contribution of the "low dose" concept.

[7] Allergan objects on evidentiary bases to Ferring's submission of testimony by Allergan's expert Dr. Sussman that Fein did not invent the doses, including on the basis that Sussman cannot testify to legal conclusions. See e.g. Allergan's 56.1 at ¶¶ 61-64. Given Allergan's admission that Fein did not recommend the doses in the '429 patent, Sussman's testimony on this point is superfluous. Furthermore, the objection necessarily admits that whether Fein invented the doses is not a disputed fact but a disputed legal conclusion, and is thus poised for resolution on a motion for summary judgment.

[8] These representations were made by Allergan's counsel at oral

"Conception is the touchstone of inventorship, the completion of the mental part of invention." Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1227-28 (Fed. Cir. 1994) (quoting Sewall v. Walters, 21 F.3d 411, 415, 30USPQ2d 1356, 1359 (Fed. Cir. 1994). Determining conception is a two-part inquiry. First, conception is defined as "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed.Cir.1986) (quoting 1 Robinson on Patents 532 (1890)); see also Dawson v. Dawson, 710 F.3d 1347, 1352 (Fed. Cir. 2013). Second, because conception is a wholly mental activity, the law requires that conception be corroborated, "preferably by contemporaneous disclosure." Burroughs Wellcome, 40 F.3d at 1228.

"Conception is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." Dawson, 710 F.3d at 1352 (quoting Burroughs Wellcome, 40 F.3d at 1228). "[A]n idea is definite and

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argument on the motion for summary judgment, held December 12, 2015. No transcript was made.

permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue." Id.

It is difficult to deem "low dose" a conception so definite that it alone and without numerical expression constitutes a complete operative pharmaceutical invention as it would be thereafter applied in practice. It is even more difficult to maintain such a position with the necessary logical analogue to Allergan's argument, that the specific doses did not constitute a conception (which, given Fein's admissions, would preclude Fein's claim of having effectively invented them by contributing the broader notion of "low dose"). Pharmaceutical companies do not sell and doctors do not prescribe "low doses," they sell and prescribe specific doses. Pharmacokinetics and pharmacodynamics, including the crucially important measure of bioavailability at issue with desmopressin, deal in specifics; rates, percentages, and observable effects resulting therefrom. A specific dose can be quite literally a matter of life or death.

Moreover, what constitutes a "low dose" must itself be determined by a specific numerical dose. "Low dose" is not alone a concept to be applied in practice, whether sale or therapeutic

use, as the law requires. Any conception of delivering a lower dose of desmopressin relative to the oral doses originally conceived by Ferring, for whatever reason, is a necessary foundational step toward a definite and permanent idea of particular low doses. However, it does not alone cross the threshold of a "complete and operative invention" capable of being applied in practice.

Allergan submitted at oral argument that the particular doses recited in the claims are insignificant, and that nobody picked these numbers. This strains credulity. At the very least, even had the idea of low dose of desmopressin been unabashedly stolen from Fein, someone must have actualized the low dose concept in to potentially administrable and patentable doses. As to significance, the evidence demonstrates that the Patent and Trademark Office ("PTO") accorded significant weight to the specific doses in the '429 patent when allowing the claims after two rejections. Allergan 56.1 at 20-21, ¶¶ 32-36. The significance of the broad concept of "low dose" with respect to desmopressin as imagined by Fein is the fact that a higher bioavailability can be achieved to allow a lower dose than previously conceptualized. Yet, the PTO considered and rejected the argument that marked increased bioavailability of the

orodispersible dose form was sufficient to defeat preclusion of the patent due to previously known research. Lloyd Decl. Ex 22 at 6. (Final Rejection of Application 10/513,437). Without the fact of increased bioavailability and without a specific dose, there is a relatively low degree of significance of low dose desmopressin as set forth in this action. Without either, "low dose" is just a general goal rather than a specific or settled idea. That two clinical studies were conducted to test bioavailability and low plasma concentrations of desmopressin after Fein purportedly contributed the low dose concept in August 2001 (at the earliest) further demonstrates that "low dose" fails the threshold of "so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." Dawson, 710 F.3d at 1352 (quoting Burroughs Wellcome, 40 F.3d at 1228).

Chronologically, the facts demonstrate that Ferring had conceived of specific low doses before corroboration shows Fein carried through the low dose concept to particular doses. Fein alleges that he first specified numerical doses of desmopressin sometime between late August 2001 and early June of 2002. Allergan 56.1 at 12 ¶ 65. However, the earliest corroboration

Allergan can provide to show when Dr. Fein proposed numerical doses is a June 6, 2002 markup of the second desmopressin study (CS009). Id. Allergan 56.1 at 12 ¶65. By then, Ferring had already filed its GB Application, which stated in part "low doses are . . . specifically contemplated, for example, from 0.5 µg to 75 µg, preferably 0.5 or 1 µg to 50 µg." GB Application (filed May 7, 2002). If the "low dose" concept was so clearly defined that translating it to particular doses was so simple "ordinary skill" could "reduce the invention to practice" without any further experimentation or research, it is difficult to imagine why Fein never mentioned any such numbers, whether to Dr. Nardi when relaying his allegedly novel invention, when he traveled to Copenhagen to remark on the concept to Ferring's European scientists, or at all until after Ferring had filed its GB Application. See Dawson, 710 F.3d at 1352; Burroughs Wellcome, 40 F.3d at 1228.

Simply put, in pharmacology the devil is necessarily in the details. It cannot possibly be that the general concept of "low dose" was the specific and sole novel aspect the invention, while the specific doses amount only to general well-known principle. Fein's admission therefore forecloses all reasonable possibility Allergan could meet the "heavy burden" of proving by

clear and convincing evidence that Fein is the sole inventor of the patent, and the presumptively correct named inventors are all incorrectly listed.

Allergan's 56.1(b) additional material facts in dispute submissions amount to a longer recitation of its brief, and are not material to whether Fein's low dose contribution—Allergan's only claim with respect to the '429 patent—might entitle him to be named as sole inventor. See Allergan 56.1 at 13-25. Because Allergan does not allege that Fein conceived of the specific doses that constitute a low dose formulation of desmopressin, there is no genuine dispute of material fact as to whether Fein can be named the sole inventor of the '429 Patent. Accordingly, summary judgment is granted in favor of Plaintiffs.

b. The '654 Patent

The '654 Patent recites 9 claims, as follows:

1. A solid orodispersible pharmaceutical dosage form comprising from 10 to 600µ desmopressin acetate, measured as the free base, which solid orodispersible dosage form disintegrates in the mouth within 10 seconds.
2. The dosage form as claimed in claim 1, which is adapted for sublingual administration.
3. The dosage form as claimed in claim 1, wherein the dosage form is obtainable by subliming solvent from a composition comprising desmopressin acetate and a solution of carrier material in a solvent, the

composition being in the solid state in a mold.

4. The dosage form as claimed in claim 3, wherein the sublimation is carried out by freeze drying a composition comprising desmopressin acetate and a solution of the carrier material in a solvent.
5. The dosage form as claimed in claim 1, which comprises an open matrix network carrying the desmopressin acetate, the open matrix network being comprised of a water-soluble or water-dispersible carrier material that is inert towards desmopressin.
6. The dosage form as claimed in claim 5, wherein the open matrix network comprises gelatin.
7. The dosage form as claimed in claim 6, wherein the gelatin is fish gelatin.
8. The dosage form as claimed in claim 7, wherein the fish gelatin is non-gelling.
9. A pack comprising an orodispersible solid pharmaceutical dosage form as defined in claim 1 together with instructions to place the dosage form in a patient's mouth beneath the tongue (for sublingual administration).

'654 Patent 18:7-36.

With respect to its claim to correct the '654 Patent to substitute Fein as the sole inventor, Allergan claims "Dr. Fein alone invented the use of low doses of desmopressin and the sublingual administration of desmopressin claimed." FAA ¶ 83. Allergan does not allege Fein made any contributions related to specific dose range, pH ranges, inactive ingredients, or any other aspects of the formulation claims. Specifically, Allergan does not dispute Fein's testimony in response to a question asking what Fein recommended as far as doses, where Fein answered "that's reflected in the markups I made in the June 6 [2002] version of the CS009 study." Allergan 56.1 at 12, ¶ 65.

As reasoned above, the fact that neither Fein nor Allergan suggest that Fein contributed the specific dose range patented alone demonstrates there is no genuine dispute of material fact as to whether Dr. Fein was the sole inventor of the '654 Patent. The additional claim of having contributed the "invention" of sublingual administration cannot sustain Allergan's claim. Because a claim of sole inventorship necessitates that the proposed inventor conceived of the total patented invention, assuming arguendo that Fein contributed a patentable invention of sublingual administration, the fact that a specific range of doses appears and Fein does not content to have contributed these doses precludes the possibility that Fein is the sole inventor.

Allergan has not pled a genuine issue of material fact as to whether Fein is the sole inventor of the '654 Patent. Summary Judgment in favor of Plaintiffs is therefore granted.

IV. Summary Judgment is Denied for the Counterclaims to Add Dr. Fein as an Inventor to the '429 and '654 Patent

Allergan's alternative claims to add Dr. Fein as an inventor of the '429 and '654 Patent are identical: "To the extent that Dr. Fein is determined not to have been solely responsible for the conception of the entire invention[s] of the [Patents], he at least made significant contributions to and collaborated with the named inventors during the conception of the invention[s] claimed." See FAA ¶78 ('429 Patent), 91 ('654 Patent).

"A joint invention is the product of a collaboration between two or more persons working together to solve the problem addressed." Burroughs Wellcome Co., 40 F.3d at 1227 (citing 35 U.S.C. § 116 (1988); Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co., 973 F.2d 911, 917, 23 USPQ2d 1921, 1926 (Fed.Cir.1992)). "People may be joint inventors even though they do not physically work on the invention together or at the same time, and even though each does not make the same type or amount of contribution." Id. However, "[o]ne who merely suggests an idea of a result to be accomplished, rather than the means of accomplishing it, is not a joint inventor." Garrett Corp. v.

United States, 422 F.2d 874, 881 (Ct. Cl. 1970) (citing Forgie v. Oil-Well Supply Co.,58 F. 871, 7 CCA 551 (3d Cir. 1893); Worden v. Fisher, 11 F. 505 (E.D.Mich. 1882)). It is the qualitative contribution of a joint inventor that matters. Burroughs Wellcome Co., 40 F.3d at 1229. "Like conception of the entire invention, a contribution to conception is a mental act which cannot be accurately verified without corroboration." Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1474 (Fed. Cir. 1997).

Ferring argues there is no genuine dispute as to whether Fein is an inventor using a divide and conquer strategy: (i) Fein, by admission, did not conceive of the specific numerical doses patented, Pls.' Mot. at 7-8, 12-14; (ii) Fein did not invent the concept of sublingual administration, id. at 9-10, 16; (iii) Fein was not involved in formulation development, id. at 10, 12; thus (iv) Fein cannot have contributed to the Patents, id. at 17. However, whether Fein alone conceived of independent concepts of low dose or sublingual administration in the patents is the inquiry relevant to whether he may be deemed the sole-inventor of these contributions, not whether he contributed qualitatively to the ultimate inventions in the Patents. Theoretically, an individual could qualitatively contribute to the inventions patented without solely conceiving

of the claimed invention, and still meet the legal burden of establishing joint inventorship. See Fina Oil & Chem., 123 F.3d at 1474 ("the doctrine of [conception] cannot be used . . . to show that because the first person did not conceive or reduce to practice the entire claimed invention, he or she did not at least contribute in some significant way to the ultimate conception.").

By declaration in support of this motion, Fein submits that in August 2001, while a consultant at Ferring, he conveyed his theory that "desmopressin was much more potent than previously recognized," and "that a much lower plasma concentration of desmopressin can achieve desirable therapeutic effects and avoid hyponatremia" to Dr. Nardi. Fein Decl. ¶¶ 7-9. Nardi informed Fein that Ferring was considering an orodispersible form of desmopressin, to which Fein "suggested to [Nardi] that the [orodispersible form] could be used to administer desmopressin through the mucosal membranes of the mouth." Id. at ¶ 10. Fein reasoned that the orodispersible form "should be administered under the tongue (i.e., sublingually) to improve bioavailability, which would permit the low doses of desmopressin while achieving a controlled and predictable concentration of desmopressin in the bloodstream." Id. Nardi

corroborates this story in his own declaration, stating that in the summer of 2001, Fein relayed his belief "that hyponatremia could be avoided by using lower doses of desmopressin, which would result in much lower plasma concentrations." Nardi Decl. at ¶¶ 9-10. Nardi also submits that Fein communicated his belief that "the orodispersible dosage form could be used for a novel sublingual delivery system for desmopressin," explaining that "sublingual delivery of the orodispersible dosage form could result in an increase in the bioavailability of desmopressin" that "would allow for the administration of lower doses." Id. at ¶ 11.

If this chain of events is factually accurate and Ferring cannot show that it conceived of pairing a lower dose of desmopressin with sublingual administration, the back and forth between Fein and Nardi appears to provide a foundation that, with additional collaboration from Ferring scientists, could amount to the ultimate patented conceptions in the '429 and '654 Patents. This is precisely the sort of collaboration in conception that the doctrine of joint inventorship addresses. Together with the collaboration of the additional inventors addressing all other novel aspects of the Patents, the team

together could be deemed to have invented the final patented conceptions in the '429 and '654 Patents.

Whether Fein's contribution was of a sufficient quality to qualify him as a joint inventor is a question of material fact. Ferring submits that it considered sublingual administration in 1990-1994 and 1999-2000, well before Fein's contribution can be corroborated, facts Allergan has admitted. Pls.' Reply at 5; Allergan 56.1 at 10, ¶¶ 52-53. It may be that Fein's contribution was therefore of little to no value, only supplying Ferring with another upside to an invention it had already conceived. It may also be that Fein's connection of sublingual administration, bioavailability, and the hyponatremia issue was of sufficient importance that they altered the ultimate claims in the Patents. Which is true is a genuine dispute of material fact about the quality of Fein's contributions. That Allergan has not yet met the high burden of correcting inventorship does not foreclose the genuine dispute of this, or any other, material fact.

Ferring argues forcefully that Fein admits he did not invent sublingual administration or the specific doses. As reasoned above, the Court agrees Fein did not conceive of the

specific doses or ranges in the Patents, but again, this fact alone does not foreclose any genuine dispute as to whether Fein contributed to the ultimate patented claims. With respect to sublingual administration, Ferring's reliance on Fein's testimony (or that of Allergan's expert Dr. Sussman) is disingenuous. Ferring, tellingly, does not submit that its scientists invented/discovered/conceived of sublingual administration either. That Fein admits he did not invent, discover, or conceive of sublingual administration is not dispositive of whether he contributed to the Patents by conceiving of applying a route of administration known in the art to desmopressin in the form and manner Allergan argues.

Ferring's construction of inventorship amounts to Ecclesiastes: "there is nothing new under the sun." 1:9. To accept it would overrule the novelty of all applications of sublingual administration (and, frankly, all other routes of administration) after the first, no matter how novel, groundbreaking, or counterintuitive to existing literature. All subsequent uses would necessarily be credited to whoever first conceived of sublingual absorption—including, it should be noted, any application of the conception by Ferring.

Ferring relies on two cases to argue that Nardi's testimony cannot provide corroboration of Fein's claim of invention. Pls.'s Reply at 10; see also Allergan, Inc. v. Apotex Inc., 754 F.3d 952, 968 (Fed. Cir. 2014) cert. denied, 135 S. Ct. 956, 190 L. Ed. 2d 832 (2015); Gerawan Farming, Inc. v. Rehrig Pac. Co., No. 1:11-CV-01273 LJO, 2013 WL 1414637, at *9-10 (E.D. Cal. Apr. 8, 2013) aff'd, 587 F. App'x 654 (Fed. Cir. 2014). The cases are inapposite. The court in Allergan v. Apotex declined to credit the corroborating testimony because it was that of another inventor, citing the Federal Circuit's skepticism for such self-serving testimony. 754 F.3d at 968 ("The only corroboration of the claimed invention is the oral testimony of an inventor, which we must treat with skepticism due to the possibility of an inventor's self-interest in obtaining or maintaining an existing patent."). Neither Ferring, nor Allergan, nor Fein, nor Nardi himself have submitted that Nardi is an inventor of any of the claims in either patent at issue. In Gerawan Farming, a nonbinding out of district case, the court found the corroborating testimony to be neither clear nor convincing due to the co-inventor's failure to provide a clear date of corroboration and lack of knowledge about the invention at issue. Gerawan Farming, 2013 WL 1414637, at *9-10 (E.D. Cal.

Apr. 8, 2013). Nardi's testimony is of a much higher caliber than the testimony in Gerawan Farming.

Considering there is a genuine dispute of material fact as to whether Fein sufficiently contributed to the ultimate inventions in the '429 and '654 Patents, summary judgment for these claims is hereby denied.

V. Conclusion

For the foregoing reasons and as set forth above, the motion for summary judgment is granted in part and denied in part.

In light of the confidentiality stipulation and order entered in this case covering the parties' submissions on this motion, the parties are directed to jointly submit a redacted version of this opinion to be filed publicly within 14 days of the date of this opinion.

It is so ordered.

New York, NY
January 7, 2016

ROBERT W. SWEET
U.S.D.J.